



UNITED STATES PATENT AND TRADEMARK OFFICE

HL

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,467	09/17/2003	William Abraham	0207.04	4350

7590 10/04/2004
Barbara G. McClung
Cygnus Inc.
Intellectual Property Dept.
400 Penobscot Drive
Redwood City, CA 94063

EXAMINER

JIANG, SHAOJIA A

ART UNIT	PAPER NUMBER
----------	--------------

1617

DATE MAILED: 10/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/664,467

Applicant(s)

ABRAHAM ET AL.

Examiner

Shaojia A. Jiang

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,9,14-16 and 28-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,9,14-16 and 28-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 9/17/03, 10/20/03.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

This application is a continuation of 09109505, which is a continuation of 08680719 which is a continuation in part of 08501664.

Applicant's preliminary amendment submitted September 17, 2003 is acknowledged wherein the instant specification has been amended as to page 1, lines 5-9 for indicating the relationship between this application and the parent cases, and page 50 line 1, replacing the title; Claims 2-3, 5-8, 10-13, and 17-27 are cancelled and claims 1, 4, 9, and 14-16 are amended; Claims 28-38 are newly submitted.

Currently, claims 1, 4, 9, 14-16 and 28-38 are pending in this application.

Claims 1, 4, 9, 14-16 and 28-38 are examined on the merits herein.

Note that the parent applications 08501664, upon which priority is claimed fail to provide adequate support under 35 U.S.C. 112 for the instant claims 1, 4, 9, 14-16 and 28-38 amended in the preliminary amendment submitted September 17, 2003 of this application. Thus, the filing date of the instant claims is deemed to be the filing date of the 08680719 filing date, 07/11/1996. If applicant disagrees, applicant should present a detailed analysis as to why the claimed subject matter has clear support in the earlier priority applications. Applicant is reminded that such priority for the instant limitations requires written description and enablement under 35 U.S.C. § 112, first paragraph.

In clarifying the priority date of the instant claims, applicant should note or address whether the art rejections are prior to the priority date of the instant claims and

whether said art occurred more than one year prior to said priority date. Applicant will note that the art rejections are under both 35 U.S.C. § 102(a) and 102(b) because the priority date of the instant claims is in question.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 4, 9, 14-16 and 28-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fox et al. (US 5,405,366, PTO-1449) in view of Janssen (EP 539625 PTO-1449) further in view of JP 56137899 (of record in the parent case).

Fox et al. discloses the hydrogel comprising (a) gel forming polymer material such polyethylene oxide (PEO) known as Polyox in an amount of 3-20 wt % of the total weight within the instant claim (see col.6 lines 63-68); (b) water in an amount from about 58 % to 96% wt of the total weight within the instant claim (see Table XIV at col.21-22; Table XVI at col.23 line 28); (c) a pharmacologically active agent; (d) sodium chloride as an electrolyte in an amount 0.1-10 wt % of the total weight overlapping with the instant claimed range; (e) a phosphate buffer that maintains a pH of the hydrogel in pH of 7 (see col.21 lines 11-49); (f) a structural support embedded in the hydrogel such as non-

woven fabric as the instantly claimed to form into patches (see abstract col.8 line 65 to col.9 line 10) ;(g) a humectant (see col.4 lines 59-64); (h) a biocide (see col.8.lines 6-24)

Fox et al. also discloses the same thickness and surface area in a range as the instant claimed (see col.8 line 60-64; col.9 line 6-10). Fox et al. also discloses the process of preparing of the hydrogels by cross-linking provided by radiation wherein using the same cross-linking agent as the instant claimed such as N,N'-methylenebisacrylamide (see Table IX at col.17-18).

Fox et al. does not expressly disclose that a pharmacologically active agent in the hydrogel is glucose oxidase or mutarotase enzyme.

Janssen discloses that hydrogel comprises glucose oxidase wherein glucose oxidase is used as catalyzer in the reaction of glucose with oxygen to produce hydrogen peroxide, used for the same purpose as the instantly claimed (see abstract and col.1 lines 22-35; claim 1).

JP 56137899 teaches that combining mutarotase with glucose oxidase increases the sensitivity of glucose determination and the mechanism. See abstract.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ a pharmacologically active agent glucose oxidase or mutarotase enzyme, in the hydrogels of Fox et al.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ a pharmacologically active agent glucose oxidase or mutarotase enzyme, in the hydrogels of Fox et al. since it is known that hydrogel comprises glucose oxidase wherein glucose oxidase is used as catalyzer in the reaction

of glucose with oxygen to produce hydrogen peroxide, as the instantly claimed, according to Janssen.

Therefore, one of ordinary skill in the art would have reasonably expected that a known and art-recognized glucose oxidase used as catalyzer in the reaction of glucose with oxygen to produce hydrogen peroxide, would have the same or substantially similar usefulness in the hydrogels of Fox et al., and that combining mutarotase with glucose oxidase would increase the sensitivity of glucose determination according to JP 56137899.

Claims 1, 4, 9, 14-16 and 28-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keusch et al. (US 5,143,071, PTO-1449) in view of Janssen (EP 539625, PTO-1449) further in view of JP 56137899 (of record) and Fox et al as discussed above.

Keusch et al. discloses the hydrogel comprising (a) gel forming polymer material such polyethylene oxide (PEO) known as Polyox in an amount of the total weight within the instant claim (see col.7 lines 14-20); (b) water in an amount of the total weight within the instant claim; (c) a pharmacologically active agent; (d) sodium chloride as an electrolyte in an amount 0.1-15 wt % of the total weight overlapping with the instant claimed range; (e) the pH of the hydrogel is about 7 since it was used *in vivo*; (f) a structural support embedded in the hydrogel such as non-woven fabric as the instantly claimed to form into patches; (g) a humectant (see col.4 lines 59-64); (h) a biocide. See col.1 line 46-col.2 line 10; col.6 line 52-col.10 line 19; col.11 line 65-col.17 line 3

Art Unit: 1617

Keusch et al. also discloses the same thickness and surface area in a range as the instant claimed (see col.8 line 60-64; col.9 line 6-10). Fox et al. also discloses the process of preparing of the hydrogels by cross-linking provided a cross-linking agent as the instant claimed such as N,N'-methylenebisacrylamide (see Table IX at col.17-18).

Keusch et al. does not expressly disclose that a pharmacologically active agent in the hydrogel is glucose oxidase or mutarotase enzyme, the buffer solution, and the particular cross-linking agent.

Janssen discloses that hydrogel comprises glucose oxidase wherein glucose oxidase is used as catalyzer in the reaction of glucose with oxygen to produce hydrogen peroxide, used for the same purpose as the instantly claimed (see abstract and col.1 lines 22-35; claim 1).

JP 56137899 teaches that combining mutarotase with glucose oxidase increases the sensitivity of glucose determination and the mechanism. See abstract.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ a pharmacologically active agent glucose oxidase or mutarotase enzyme, in the hydrogels of Keusch et al.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ a pharmacologically active agent glucose oxidase or mutarotase enzyme, in the hydrogels of Keusch et al. since it is known that hydrogel comprises glucose oxidase wherein glucose oxidase is used as catalyzer in the reaction of glucose with oxygen to produce hydrogen peroxide, as the instantly claimed, according to Janssen.

Therefore, one of ordinary skill in the art would have reasonably expected that a known and art-recognized glucose oxidase used as catalyzer in the reaction of glucose with oxygen to produce hydrogen peroxide, would have the same or substantially similar usefulness in the hydrogels of Keusch et al., and that combining mutarotase with glucose oxidase would increase the sensitivity of glucose determination according to JP 56137899.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 4, 9, 14-16 and 28-38 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 6,735,273 in view of Janssen (EP 539625, PTO-1449) further in view of JP 56137899 (of record).

Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent is drawn to an assembly or sensor or patch comprising the same hydrogels used for the same purpose as the instant claimed.

Thus, the assembly or sensor or patch in the patent encompasses the same hydrogels in the instant application.

Thus, the instant claims 1, 4, 9, 14-16 and 28-38 are seen to be obvious over the claims 1-20 of U.S. Patent No. 6,735,273 in view of Janssen (EP 539625, PTO-1449) further in view of JP 56137899 (of record) as discussed above.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (571)272-0627. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703.872.9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Application/Control Number: 10/664,467

Page 9

Art Unit: 1617

A handwritten signature in black ink, appearing to read 'S. Anna Jiang', with a long, sweeping horizontal line extending to the right.

S. Anna Jiang, Ph.D.

Primary Examiner, AU 1617

September 24, 2004